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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/373,182	08/12/1999	KIM MCCLURE	PC10240A	2284

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EXAMINER

WEBER, JON P

ART UNIT PAPER NUMBER

1651

DATE MAILED: 11/19/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Applicati n No.

09/373,182

Applicant(s)

MCCLURE ET AL.

Examiner

Jon P Weber, Ph.D.

Art Unit

1651

--The MAILING DATE of this communicati n appears n the c ver sheet with the correspondence address --

THE REPLY FILED 21 October 2002 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 21 October 2002. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____

3. ☐ Applicant's reply has overcome the following rejection(s): _____.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See attachment.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

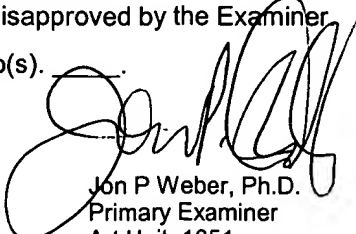
Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: 61 and 81.

Claim(s) withdrawn from consideration: _____.

8. ☐ The proposed drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s).
10. ☐ Other: _____


Jon P Weber, Ph.D.
Primary Examiner
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Status of the Claims

The response with amendments filed 21 October 2002 has been received and entered. Claims 61 and 81 have now been presented for examination.

Claim Rejections - 35 USC § 112

Claims 61 and 81 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for certain compounds which exhibit 100-fold or 500-fold selectivity for TACE over MMP1, does not reasonably provide enablement for any compound which exhibits said selectivity. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and or use the invention commensurate in scope with these claims.

The response makes the same arguments as before, that assays are provided that can be used to determine if a compound meets the claim limitations or not. It is further argued that the instant claims are limited to hydroxamate compounds, a structural feature. It is also argued that compounds that inhibit TACE are disclosed in a number of patents. It is also argued that compounds that meet the claim limitations are disclosed.

As indicated in the previous Office action, the disclosure has not provided any means or structural feature for identifying a compound that exhibits the desired degree of selectivity between TACE and MMP1. It is known that both of these enzymes are metalloproteinases. It is also well known in the art that hydroxamates are inhibitors of metalloproteinases. Hence, there is no question but that the claims are enabled for hydroxamates that inhibit both enzymes. However, the question raised by the Office actions of 16 April 2002 and 11 July 2001 is whether

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the claims are enabling commensurate to the claimed scope. The issue is whether the disclosure is sufficient to enable the functional limitation of being 100- or 500-fold more selective for TACE over MMP-1. The fundamental element of the Wands factors is predicatability compared to the showings and teachings in the disclosure and the prior art. It is clear that the prior art is silent in this regard and cannot provide enablement for the claims. This is precisely why there is no prior art cited against the claims. One must therefore rely exclusively for the teachings in the disclosure. What one finds is several compounds which meet the functional limitations but for which there is no extrapolatable structural element that leads one to obtain a hydroxamate inhibitor that meets the functional limitations of the claims. In fact, the silence of the prior art on the desired degree of selectivity between these two enzymes makes it impossible to know if there are already known compounds that have been disclosed to inhibit one or the other of these two enzymes that already meet the functional limitations of the claims. As already discussed, "make and test" is not the standard under 112, first paragraph.

Applicant's arguments filed 21 October 2002 have been fully considered but they are not persuasive. The rejection under 35 U.S.C. 112, first paragraph is adhered to for the reasons of record and the additional reasons above.

No claims are allowed.